II. RESPONSE TO OFFICE ACTION

A. Status of the Claims

Claims 39-47 and 63-88 were pending prior to the Office Action dated March 3, 2005. Claims 39 and 68 have been amended. Claim 89 has been added. Support for the amendments may be found in the specification at least at page 8, lines 27-29; page 27, lines 1-20; page 69, lines 16-20; page 72, lines 16-17. No new matter has been added.

B. Claims Are Adequately Described

The Action rejects claims 39-47, 63-83, and 84-87 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Action contends that the term "a Fortilin polypeptide" encompasses variants of Fortilin that are biologically active and that there is no structure function relationship such that one of skill in the art could be able to clearly recognize any critical structural elements of Fortilin.[1] Applicants respectfully traverse this rejection.

The Federal Circuit has stated that the test for the written description requirement is "whether the application relied upon 'reasonably conveys to the artisan that the inventor had possession at the time of the later claimed subject matter.'" *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790 (Fed. Cir. 1998). *See also Markman v. Westview Instruments, Inc.* 52 F.3d 967, 34 USPQ 2d 1321 (Fed. Cir. 1995) (en banc) ("Claims must be read in view of the specification, of which they are a part."). In rejecting a claim under the written description requirement of 35 U.S.C. §112, first paragraph, the Examiner has the initial burden of presenting

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[1] As a side issue, Applicants dispute the contention in the Action that "the phrase 'a Fortilin polypeptide' implies there is more than one Fortilin polypeptide." Action at page 3. The term may or may not mean "more than one Fortilin polypeptide." The specification indicates that consistent with patent law, the term "a" may mean "one," but it is also consistent with the meaning of "one or more," "at least one," and "one or more than one." Specification at page 10, lines 24-26.

evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined in the claims. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). Accordingly, the Examiner is required: (1) to set forth the claim limitation not described; and (2) to provide reasons why a person skilled in the art would not have recognized the description of the limitation in view of the disclosure of the application as filed. *Interim Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, Paragraph 1*, Chisum on Patents, vol. 3, §7.04[1][c]. The Guidelines state that the "written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, **or** by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus." (Emphasis added). While a structure/function relationship may be relied upon to satisfy the written description requirement, it is not absolutely required.

In this case, the claims recite a method involving a polypeptide with specific structural and chemical properties. The polypeptide is one "that is at least 70% identical or functionally equivalent to SEQ ID NO:2 or that has at least 20 contiguous amino acids from SEQ ID NO:2." The specification fully discloses SEQ ID NO:2. The specification fully supports any polypeptide that meets the limitations of the claims. In fact, from a pure mathematical point of view, the number of species disclosed by the specification with respect to each claim is numerous. A person of ordinary skill in the art would understand that the specification disclosed at least *thousands* of different species with respect to SEQ ID NO:2. Even an individual who is only

minimally skilled in the art could identify many different species that satisfied the claims based simply on the disclosed sequence. Based on the number of disclosed species, the specification necessarily satisfies the written description requirement because it reasonably conveys to one of skill in the art that they had possession of the claimed subject matter. *In re Daniels*, 144 F.3d 1452, 1456, 46 USPQ2d 1788, 1790.

C. Claims Are Sufficiently Enabled

The Action rejects claims 39-47, 63-83, and 84-87 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The reasons are for the same reasons set forth in the written description rejection. In addition to the reasons presented above, Applicants provide the following arguments.

In examining a patent application, the PTO is required to assume that the specification complies with the enablement provisions of § 112 unless it has "acceptable evidence or reasoning" to suggest otherwise. *In re Marzocchi*, 439 F.2d 220, 223-24, 169 USPQ 367, 369-370 (CCPA. 1971). Thus, the PTO must provide reasons supported by the record as a whole what the specification is not enabling. *Application of Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219-220 (CCPA 1979). Then, and only then, does the burden shift to the applicant to show that one of ordinary skill in the art could have practiced the claimed invention without undue experimentation. *In re Strahilevitz*, 668 F.2d. 1229, 1232, 212 USPQ 561, 563-64 (CCPA 1982) In this case, evidence to support any allegations has not been provided. If the rejection is to be maintained, the Examiner must support this position by citing published references or by Examiner's Affidavit, as required by MPEP 2144.03.

The present claims recite a method for identifying a modulator of a Fortilin polypeptide. The examiner has not provided any evidence that a person of skill in the art would not be able to

practice the claimed invention. There is not evidence that a skilled artisan could not take a Fortilin polypeptide as previously claimed or as now claimed to identify a modulator of a Fortilin polypeptide.

Moreover, as discussed above, the instant claims are directed to a "Fortilin polypeptide that is at least 70% identical or functionally equivalent to SEQ ID NO:2 or that has at least 20 contiguous amino acids from SEQ ID NO:2." The issue is whether the specification teaches one of ordinary skill in the art how to make and use such polypeptides without "undue experimentation." MPEP 2164.08 (citing *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q. 1510, 1513 (Fed. Cir. 1993)).

Undoubtedly, the inquiry must focus on the limitations of the claims. In this case, it is clear that the specification teaches how to make a "Fortilin polypeptide" that has "is at least 70% identical or functionally equivalent to SEQ ID NO:2" or that has "at least 20 contiguous amino acids from SEQ ID NO:2." The specification provides SEQ ID NO:2 and a cDNA sequence encoding SEQ ID NO:2 (shown as SEQ ID NO:1). Moreover, it identifies amino acid substitutions that are conservative and would be expected to yield biologically functionally equivalents. See page 27. In addition, the specification sets forth Examples in which data is provided regarding regions of the Fortilin polypeptide that are needed for its activity. Amino acids 5-22 of Fortilin are believed necessary for binding with MCL1. Page 166. Also, there is data regarding different deletion constructs and their ability to prevent apoptosis in Example 22. Page 168.

Moreover, FIG. 1 compares the sequence of a number of Fortilin polypeptides from a variety of organisms. The sequences of eight different polypeptides are compared, including

several mammalian Fortilin polypeptides (human, rabbit, and mouse). The identical and homologous amino acids between the sequences are highlighted in black and gray, respectively.

Therefore, at the time the application was filed, a person of ordinary skill in the art could make the claimed polypeptides based on information provided in the specification and what was known at that time. In addition to disclosing the polypeptide sequences, the application provides information about domains and functions, as well as conserved amino acids.

CONCLUSION

Applicants believe that the foregoing remarks fully respond to all outstanding matters for this application. Applicants respectfully request that the rejections of all claims be withdrawn because they are in condition for allowance. At the very least, Applicants request entry of these amendments in order to place the case in better form for an appeal.

Should the Examiner desire to sustain any of the rejections discussed in relation to this Response, the courtesy of a telephonic conference between the Examiner, the Examiner's supervisor, and the undersigned attorney at 512-536-3081 is respectfully requested.

Respectfully submitted,

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Date: May 11, 2005